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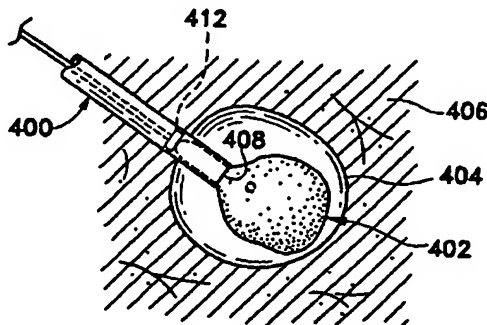
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[Continued on next page]

(54) Title: **DEVICE AND METHOD FOR SAFE LOCATION AND MARKING OF A CAVITY AND SENTINEL LYMPH NODES**



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(57) Abstract: Cavity and sentinel lymph node marking devices, marker delivery devices, and methods are disclosed. More particularly, upon insertion into a body, the cavity marking device and method enable one to determine the center, orientation, and periphery of the cavity by radiographic, mammography, echogenic, or other noninvasive imaging techniques. A composition and method are disclosed for locating the sentinel lymph node in a mammalian body to determine if cancerous cells have spread thereto. The composition is preferably a fluid composition consisting of a carrier fluid and some type of contrast agent; alternatively, the contrast agent may itself be a fluid and therefore not need a separate carrier fluid. This composition is capable of (1) deposition in or around a lesion and migration to and accumulation in the associated sentinel node, and (2) remote detection via any number of noninvasive techniques. Also disclosed is a method for remotely detecting the location of a sentinel node by (1) depositing a remotely detectable fluid in or around a lesion for migration to and accumulation in the associated sentinel node and (2) remotely detecting the location of that node with a minimum of trauma and toxicity to the patient. The composition and method may serve to mark a biopsy cavity, as well as mark the sentinel lymph node. The marking methods also may combine any of the features as described with the marking device and delivery device.



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(AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 99/30619

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/00 A61B8/00 A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, INSPEC

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y A X	WO 98 47430 A (VASCULAR SCIENCE INC) 29 October 1998 (1998-10-29) page 5, line 11 -page 6, line 14 page 8, line 30 -page 11, line 34; figures claim 7	1,7-12, 61-63 3,25-40, 51,52,60  223
Y A	EP 0 534 696 A (ERLEBACHER JAY ;GOLDWEIT RICHARD S (US)) 31 March 1993 (1993-03-31) column 3, line 43 - line 52 column 6, line 44 -column 7, line 55; figures  -/-	1,7-12, 61-63 15-22,34



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

### \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principles or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"Z" document member of the same patent family

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23 August 2000

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30.08.2000

Name and mailing address of the ISA

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## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/30619

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 108 421 A (FOWLER BRADFORD C) 28 April 1992 (1992-04-28) column 5, line 29 -column 6, line 51; figures	1,7-12, 25-28
X	column 1, line 13 - line 30  column 5, line 63 -column 6, line 51	84,85, 92,93, 123
A	US 4 787 391 A (ELEFTERIADES JOHN A) 29 November 1988 (1988-11-29)  column 3, line 34 -column 4, line 48; claims; figures	1-3, 7-12, 26-28
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A	US 5 670 161 A (HEALY KEVIN E ET AL) 23 September 1997 (1997-09-23) abstract; claims; figures	1
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X	WO 96 08208 A (BIOPSY MEDICAL INC) 21 March 1996 (1996-03-21)  page 17, line 25 -page 18, line 15; claims; figures	84-87, 91,93, 94,100, 110,119, 120,123, 124,127, 128 60,79,82
X	DE 44 03 789 A (SCHERING AG) 10 August 1995 (1995-08-10) column 3, line 55 - line 68 column 7, line 10 - line 35	65,66, 69,71,72
X	DE 43 30 958 A (SCHERING AG) 16 March 1995 (1995-03-16) column 3, line 8 -column 4, line 5 column 9, line 1 - line 20	65,66, 68-72
	-/-	

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 99/30619

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DUFRANE P ET AL: "PREBIOPSY LOCALIZATION OF NON-PALPABLE BREAST CANCER" JOURNAL BELGE DE RADIOLOGIE, XX, XX, vol. 73, no. 5, 1 October 1990 (1990-10-01), pages 401-404, XP000513990 the whole document	65, 67
X	EP 0 769 281 A (UNITED STATES SURGICAL CORP) 23 April 1997 (1997-04-23) column 10, line 12 -column 12, line 14; figures	84, 85, 88, 91
X	US 4 230 123 A (HAWKINS JR IRVIN F) 28 October 1980 (1980-10-28) column 2, line 65 -column 4, line 9; figures	84, 85, 88, 89
A	US 5 394 886 A (NABAI HOSSEIN ET AL) 7 March 1995 (1995-03-07) the whole document	224

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 99/30619

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 130-220  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☒ Claims Nos.: 13-22, 64, 73-78  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-12,23-59, 61-63

marking device of resilient bioabsorbable material with a marker

2. Claim : 60

marking device of nonbioabsorbable suture material and marker

3. Claims: 65-78,221,222

composition comprising nontoxic detectable microparticles

4. Claims: 79-83,126,129

marking delivery device with cartridge

5. Claims: 84,85-93,123,125,127,129

marking delivery device with outer sheath for use with amedical instrument

6. Claims: 84,94-118,120-122,124,125,128,129

marking delivery device with a flexible shaft protion

7. Claims: 84,119

marking delivery device preloaded with a marking device

8. Claim : 223

process for making a marking device by placing a marker on a sheet

9. Claims: 224,225

process of making a marking device by cutting a filler body and creating a hole therein.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box 1.2

Claims Nos.: 13-22, 64, 73-78

Claims 13 to 22 and 64 and so the claims 73-78 (dependent on claim 64) are not clear (in the sense of Article 6 PCT) in that they do not define device features, but define a device merely by results to be achieved when using the device. In particular, it is unclear how the device is restricted by the mere desiderata of the body is "palpable" and "degradable" over some periods of time.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.



# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/30619

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